



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,261	12/09/2003	Stephen M. Testa	50229-418	3335

7590 05/03/2006

MCDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, DC 20005-3096

EXAMINER

VIVLEMORE, TRACY ANN

ART UNIT	PAPER NUMBER
----------	--------------

1635

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/730,261

Applicant(s)

TESTA ET AL.

Examiner

Tracy Vivlemore

Art Unit

.1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-27 is/are pending in the application.
- 4a) Of the above claim(s) 10-24,26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection not reiterated in this Action is withdrawn.

Election/Restrictions

Claims 10-24, 26 and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 29, 2005.

Claim Rejections - 35 USC § 112

Claims 1-7, 9 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 25 recite a trans-excision splicing ribozyme that splices the 5' end of the substrate created by the excision to the ωG of the 3' end of the substrate created by the excision. This claim is indefinite because during the excision reaction the cleavage of the substrate creates two new substrates, each of which has a 5' and a 3' end. The metes and bounds of the claim cannot be determined because it is unknown which substrate 5' end is spliced to which substrate 3' end.

Additionally, the claim recites that the 5' end of the substrate is spliced to the ω G of the 3' end of the substrate. ω G is a term recognized by those of skill in the art as referring to the G residue in the portion of the intron removed in the final step of the group I intron splicing reaction. Because the art recognizes ω G as a term used to describe part of the excised sequence, it is unknown if the claims are meant to be limited to the only those embodiments in which the trans-excision splicing ribozyme creates a U-G bond between the spliced segments or if the instant ribozyme is splicing to the ω G present at the end of the non-native target RNA sequence.

Claims 2-7 and 9 are indefinite for the same reasons due to their dependence from claim 1.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites the limitation "the response elements" in line 1. There is insufficient antecedent basis for this limitation in the claim. Additionally, claim 9 refers to the ribozyme of claim 1 and has been amended to recite that the response elements are separated by a bridging sequence. Applicant points to figure 1b as providing support for the amended claim. This figure shows a bridge between 5' and 3' exon regions but does not illustrate any structure within the ribozyme that is a bridging sequence.

Art Unit: 1635

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claimed invention is directed to a modified trans-excision splicing group I ribozyme that performs a first catalytic step in the absence of a guanosine cofactor and catalyzes a sequence specific excision of a non-native target RNA sequence. In specific embodiments the excised sequence is a single nucleotide, a premature stop codon, or a frameshift mutation. In other embodiments the modified ribozyme recognizes and removes the triplet expansion region associated with muscular dystrophy. The claims encompass any modified group I ribozymes that don't require a guanosine cofactor.

The prior art describes the structures of self-splicing group I introns from numerous organisms and also describes (see for example, Cech et al. Nucleic Acids and Molecular Biology, vol. 10, of record) that group I introns require a guanosine cofactor as a nucleophile for the first step of the splicing reaction.

The specification describes the structure of one ribozyme derived from the group I intron motif of the pathogen *P. carinii* that has been modified to perform a trans-

Art Unit: 1635

excision splicing reaction. The specification describes that the exemplified modified ribozyme performs the first step of the excision reaction in a guanosine independent fashion. The specification does not describe what structure within the modified group I ribozyme confers the function of performing the first catalytic step in a guanosine independent manner. Without a description of the structure that confers guanosine independence to a modified group I ribozyme, the skilled artisan cannot envision the structure of the full genus of modified group I ribozymes encompassed by the claims.

Both the specification and the prior art are silent with regard to whether wild-type *P. carinii* group I introns splice in the absence of guanosine cofactors but the prior art disclosures of such reactions use these cofactors. It is unknown if all group I ribozymes derived from *P. carinii* would exhibit guanosine independence. Therefore, the exemplified modified *P. carinii* group I ribozyme does not provide a representative sample of modified *P. carinii* ribozymes that catalyze in the absence of a guanosine cofactor encompassed by the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The central FAX Number is 571-273-8300.

Art Unit: 1635

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
April 28, 2006


JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER